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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/716,417

11/20/2003

Takeo Tanaami

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EXAMINER

BOWERS, NATHAN ANDREW

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/716,417	<b>Applicant(s)</b> TANAAMI ET AL.	
	<b>Examiner</b> Nathan A. Bowers	<b>Art Unit</b> 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 30 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 2 and 4-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2, 4-13 and 19-25 is/are rejected.
- 7) ☒ Claim(s) 14-18 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1) Claims 1-8, 10, 11 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Christian (US 4708931) in view of Schembri (US 20040087033), Applicant's admitted prior art, Wilding (US 20060223166), Anderson (US 20050202504) and Childers (US 20040086872).

With respect to claims 1 and 2, Christian discloses a biochip cartridge comprising a tabular substrate member (Figure 13:121). A flexible cover (Figure 13:150) is airtightly attached to the surface of the substrate member. The substrate includes an area (Figure 12:122) for detecting desired biopolymers. Christian additionally discloses additional areas (Figure 12:125 and Figure 12:124 and Figure 12:123) that are fully capable of storing biopolymers and preprocessing biopolymers. Christian additionally discloses that flow paths (Figure 12:133 and Figure 12:132 and Figure 12:131) for connecting these areas are formed in the substrate member. This is taught in column 12, line 15 to column 13, line 5. Christian, however, does not expressly disclose that the substrate is formed using an elastic material.

Schembri discloses an elastic substrate (Figure 4:334). A plurality of channels and chambers (Figure 4:340) are formed in the substrate. The substrate is capable of

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accommodating an area (Figure 4:332) for detecting desired biopolymers. This is disclosed in paragraphs [0087]-[0091].

At the time of the invention, it would have been obvious to create the tabular substrate disclosed by Christian from an elastic material. In paragraph [0006], Schembri indicates that flexible substrates are known in the art to be advantageous over rigid substrates in a variety of ways. Flexible substrates are more convenient and less costly to handle during manufacturing. Furthermore, elastic substrates are beneficial because they can conform to the contour of a variety of support surfaces, and are less likely to break under impact.

The combination of Christian and Schembri still differs from the claimed invention because Christian and Schembri do not expressly indicate that biopolymers and biopolymer solutions are transferred sequentially from a storage area to a preprocessing area to a detection area to a waste reservoir in a time-differentiated manner.

Applicant discloses that it is known in the art to prepare biochip cartridges comprising a tabular substrate member attached to a flexible cover in an airtight manner. The use of fluidly connected storage (Figure 5:43), preprocessing (Figure 5:44) and detection (Figure 5:45) areas is also known. This is taught on pages 3 and 4 of the specification. Applicant further discloses on page on page 4 of the specification that it is well known in the art to use a waste liquid reservoir (Figure 5:47) for storing drainage from the detection area.

Wilding discloses a biochip cartridge comprising a collection area (Figure 16:22A), a preprocessing area (Figure 16:22B and Figure 16:16B) and a detection area (Figure 16:40) arranged in series. This is disclosed in paragraphs [0083]-[0085].

Anderson discloses a biochip cartridge comprising a collection area (Figure 3:202), a preprocessing area (Figure 3:206-214) and a detection area (Figure 3:218) arranged in series. This is disclosed in paragraphs [0167]-[0172].

Childers discloses a biochip cartridge comprising a collection area (Figure 5:118), a preprocessing area (Figure 3:120) and a detection area (Figure 3:68) arranged in series. This is disclosed in paragraph [0060].

At the time of the invention, it would have been obvious to alter the arrangement of channels and chambers in the apparatus disclosed by Christian in order to ensure that biopolymers and biopolymer solutions are transferred sequentially from a storage area to a preprocessing area to a detection area to a waste reservoir in a time-differentiated manner. As evidenced by Wilding, Anderson and Childers, this arrangement is considered to be well known in the art. This would have been beneficial because it would have guaranteed that biopolymers are adequately treated to promote increased detection before they are moved into the hybridization area. The admitted prior art in particular suggests that it is known to sequentially move biopolymers through storage and preprocessing areas before arrival at the detection area.

With respect to claims 3-5, 7 and 13, Christian, Schembri, the admitted prior art, Wilding, Anderson and Childers disclose the apparatus set forth in claim 2 wherein the biopolymers are transferred by pressing the cover with a roller-like rigid body (Figure

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13:130), and squeezing each gap formed in the substrate member. This is disclosed by Christian in column 12, line 41 to column 13, line 5.

With respect to claim 6, Christian, Schembri, the admitted prior art, Wilding, Anderson and Childers disclose the apparatus in claim 2 wherein a cover is attached to both the top and bottom surfaces of the substrate member. Figure 13 of Christian indicates that the bottom and top surfaces of the substrate are sealed by cover members 152 and 150, respectively.

With respect to claim 8, Christian, Schembri, the admitted prior art, Wilding, Anderson and Childers disclose the apparatus in claim 6 wherein the covers are formed using plastics. In column 12, lines 64 and 65, Christian indicates that the covers are made from suitable flexible materials. In column 14, lines 39-54, Christian additionally indicates that the cover members 14' and 40' of a similar biochip cartridge are made from suitable plastic materials.

With respect to claim 9, Chris Christian, Schembri, the admitted prior art, Wilding, Anderson and Childers disclose the apparatus set forth in claim 6 as set forth in the 35 U.S.C. 103 rejection above. Anderson additionally discloses in paragraph [0172] that it is known in the art to provide covers that are is transparent to facilitate optical detection. Applicant's admitted prior art additionally teaches that transparent cover materials are well known.

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With respect to claim 10, Ch Christian, Schembri, the admitted prior art, Wilding, Anderson and Childers disclose the apparatus set forth in claim 3 as set forth in the 35 U.S.C. 103 rejection above. In addition, Applicant's admitted prior art teaches on pages 4 and 5 that pockets (Figure 5:48, 50) for storing preprocessing solutions are formed in different positions so that when the substrate member is squeezed, a preprocessing solution is released in a time differentiated manner.

With respect to claim 11, Christian, Schembri, the admitted prior art, Wilding, Anderson and Childers disclose the apparatus set forth in claim 2 as set forth in the 35 U.S.C. 103 rejection above. Although the above references do not disclose that the substrate is formed into a wedge shape, this embodiment of the invention would not change the function of the device in an unexpected manner. In *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 830, 225 USPQ 232 (1984), the Federal Circuit held that, where the only difference between the prior art and the claims was the recitation of relative dimensions that do not alter performance, the claimed device is not patentably distinct from the prior art. Accordingly, the claimed wedge shape is considered not to be patentably distinct from the substrate disclosed by Christian.

With respect to claim 12, Christian, Schembri, the admitted prior art, Wilding, Anderson and Childers disclose the apparatus set forth in claim 2 as set forth in the 35 U.S.C. 103 rejection above. In addition, Applicant teaches on page 5 that the use of a valve for checking the flow of solutions is well known in the art. Applicant states that the

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valve opens when a solution flowing through the flow path is pressurized. Wilding, Anderson and Childers each teach that it is known in the art to provide valves within various flow paths.

2) Claims 19-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Christian (US 4708931) in view of Schembri (US 20040087033), Applicant's admitted prior art, Wilding (US 20060223166), Anderson (US 20050202504) and Childers (US 20040086872) as applied to claims 1 and 2, and further in view of McGarry (US 6642046).

With respect to claims 19 and 20, Christian, Schembri, the admitted prior art, Wilding, Anderson and Childers disclose the apparatus set forth in claim 2 as set forth in the 35 U.S.C. 103 rejection above. Christian additionally indicates that biopolymer microarrays are mounted on a slide that is 0.127 mm wide and 0.761 mm long. Christian, however, does not expressly disclose that a carrier is a glass slide.

McGarry discloses a biochemical detection device in which biopolymer microarrays are mounted on a glass slide (Figure 2:20). The glass slide is mounted upon a substrate (Figure 1:32) in such a way that the microarrays located on the glass slide are opposite the surface (Figure 1:34) of the substrate. The glass slide and substrate form a reaction area (Figure 10:30) in which hybridization occurs. This is disclosed in column 5, line 51 to column 6, line 10. McGarry teaches in column 8, lines 23-39 that the dimensions of the glass slide are no greater than 25 mm wide by 75 mm long.

At the time of the invention, it would have been obvious to fashion the microarray carrier disclosed by Christian from a glass slide. This is due to the fact that glass is a



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rigid and inert substrate that is capable of covalently bonding to biochemical probes. Glass is relatively inexpensive and easily attained. The use of glass to accommodate the reactive surface of hybridization reaction chambers is well known in the art. Minimizing the size of the glass slide would also have been advantageous because it would have allowed one to reduce the volume of the hybridization detection area. This would have reduced the amount of sample needed to conduct the experiment, and would have reduced costs associated with the purchase of reagents.

With respect to claims 21, Christian, Schembri, the admitted prior art, Wilding, Anderson, Childers and McGarry disclose the apparatus set forth in claim 19 as set forth in the 35 U.S.C. 103 rejection above. In addition, the admitted prior art discloses that a collection area (Figure 5:43) for storing biological samples, a preprocessing solution storage area (Figure 5:44) for storing preprocessing solutions, a plurality of washing solution storage areas (Figure 5:48, 50), a combination/detection area (Figure 5:45) for performing hybridization reactions, and a waste liquid reservoir (Figure 5:47) are all provided for within the biochip cartridge. This is disclosed in column 9, line 33 to column 10, line 15. A flow path connecting all the areas and storages in series is provided.

With respect to claim 22, Christian, Schembri, the admitted prior art, Wilding, Anderson, Childers and McGarry disclose the apparatus set forth in claim 19 as set forth in the 35 U.S.C. 103 rejection above. In addition, the prior art discloses that the biological samples are transferred by squeezing the substrate member with a rigid roller

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(Figure 6:41) in the direction from the collection area toward the combination area. This is disclosed on page 5 of Applicant's specification.

With respect to claims 23 and 24, Christian, Schembri, the admitted prior art, Wilding, Anderson, Childers and McGarry disclose the apparatus set forth in claim 19 as set forth in the 35 U.S.C. 103 rejection above. Furthermore, McGarry teaches that the glass slide biopolymer microarray (Figure 1:20) is mounted on the substrate member (Figure 1:32) in such a manner that the array area of the glass slide is opposed to the combination area (Figure 6:30). Additionally, a cover (Figure 1:54) formed of rigid material is attached to the substrate so that a cavity is formed therebetween.

At the time of the invention, it would have been obvious to form the hybridization/combination area disclosed by Christian from a glass slide microarray supported by a rigid cover and positioned oppositely from the substrate. This would have been beneficial because it would have created a sturdy reaction chamber within which hybridization can be monitored. The rigid cover member would have been able to provide a backing to the glass slide microarray, upon which pressure could be transmitted to force the glass slide into an airtight seal with the substrate. The subsequently formed hybridization and combination area can be constructed to be microfluidic in size, which would decrease expenses associated with the purchase of reagents.

With respect to claim 25, Christian, Schembri, the admitted prior art, Wilding, Anderson, Childers and McGarry disclose the apparatus set forth in claim 19 as set forth in the 35 U.S.C. 103 rejection above. In addition, the prior art teaches on pages 3 and 4

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of Applicant's specification that DNA and RNA extraction mechanisms are well known, and are practiced during preprocessing operations.

***Allowable Subject Matter***

Claims 14-18 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

With respect to claim 14, the cited prior art does not disclose, in the claimed environment, the use of a biochip cartridge that includes a tabular substrate and flexible cover that are made separable into a first and second housing. The Furcht reference discloses a gene strip 11 that is removably inserted into a test card 14 in order to allow sample fluids to move from the gene strip to the test card. However, Furcht gives no indication that it would be possible to construct multiple separable housing units in an apparatus comprising an elastic, tabular substrate and a flexible cover. Thus, the teachings of Furcht are incompatible with the teachings of Christian.

***Response to Arguments***

Applicant's arguments filed 29 December 2006 with respect to the 35 U.S.C. 103 rejections involving the combination of Christian, Schembri, Applicant's admitted prior art, Wilding and Anderson have been fully considered but are not persuasive.

*Applicant's principle arguments are*

*(a) If Christian was modified as per the suggestion of the Office Action, waste and/or sample solution would likely leak out of opening 126, thus creating a biohazard risk.*

In response to Applicant's arguments, please consider the following comments.

There doesn't seem to be any support for this assertion in Applicant's remarks. Wilding and Anderson each teach that it is known in the art to remove waste and/or sample solution from a detection area in a controlled manner. There appears to be no reason to believe that Christian's apparatus is particularly prone to leakage.

*(b) If Christian were modified according to the suggestion of the Office Action, the sample solution would flow not only into a side of the microassay rod 10, but also would flow into the wash chambers 123 and 125, and the detection solution chamber 124. Finally, the solutions from wash chambers 123 and 125 and detection solution chamber 124 would flow into the proposed "pre-processing areas."*

In response to Applicant's arguments, please consider the following comments.

It appears that Applicant is concerned with the diagram presented on page 13 of the previous Office Action the describes what the proposed combination of Christian, Schembri, Applicant's admitted prior art, Wilding and Anderson would look like. Based on this figure, it does seem like it would be possible for sample solution to be accidentally diverted into the wash chambers. However, it is important to remember that this figure was created simply to further describe the serial flow pattern generally without showing every technical feature.

Clearly, Applicant's admitted prior art, Wilding and Anderson each disclose schematics in which sample solution flows directly from a pre-processing area to a detection area without being redirected into a wash solution chamber. In light of these references, one of ordinary skill in the art would recognize how to redesign the apparatus of Christian to ensure that the sample is not needlessly moved into the wash chambers.

*(c)The proposed modification of Christian would change the principles of operation of the device. The modification would moving from a "parallel" configuration to a "series" configuration, the utilization of a pump rather than a roller, and the use of a bag rather than a tabular substrate.*

In response to Applicant's arguments, please consider the following comments.

It is agreed that the redesign of Christian would require changing the principle of operation from a biochip in which reagents are moved in "parallel" to one in which reagents are moved in "series." However, this does not constitute a substantial reconstruction and redesign. Rather, such a change in design is a simple rearrangement of parts that results in an improved apparatus. The new design would have been beneficial because it would have guaranteed that biopolymers are adequately treated to promote more effective detection before they are moved into the hybridization area.

Additionally, the redesign of Christian would in no way require the use of a pump in place of a roller, or the use of a bag instead of a tabular substrate. There is no evidence presented that indicates that a serial channel and chamber design requires the use of a pump and bag.

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*Conclusion*

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

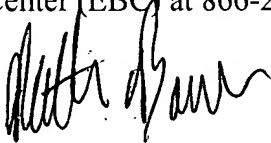
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan A. Bowers whose telephone number is (571) 272-8613. The examiner can normally be reached on Monday-Friday 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on (571) 272-1226. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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NAB

A handwritten signature in black ink, appearing to read "Gladys J. Corcoran".

GLADYS J. CORCORAN  
SUPERVISORY PATENT EXAMINER